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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,897	04/02/1999	KATSUMI AOYAGI	4047	1769
1109	7590	09/15/2004	EXAMINER	
ANDERSON, KILL & OLICK, P.C. 1251 AVENUE OF THE AMERICAS NEW YORK, NY 10020-1182			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/269,897	AOYAGI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 July 2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 4,11,12,34,37,38 and 41 is/are pending in the application.

4a) Of the above claim(s) 12 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 4,11,34,37,38 and 41 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The amendment and response filed on 7-2-2004 are acknowledged. Claims 4, 11, 34, 37-38 and 41 have been amended. Claim 12 remains withdrawn from consideration. Claims 4, 11, 34, 37-38 and 41 are currently under examination.

### ***Claim Rejections Withdrawn***

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite since it was dependent on a canceled claim is withdrawn in light of the amendment thereto.

The rejection of claim 34 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite since it was dependent on a canceled claim is withdrawn in light of the amendment thereto.

The rejection of claim 38 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite since it was dependent on a canceled claim is withdrawn in light of the amendment thereto.

The rejection of claims 11, 37 and 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “in the presence of” is withdrawn in light of the amendment thereto.

### ***Claim Rejections Maintained and New Grounds of Rejection***

#### ***35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) still contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

**Applicant argues:**

1. The probe antibody in step (1) is limited to monoclonal antibodies.
2. The claimed method consists of three steps: treating sample comprising HCV or HBV with a treatment solution (steps 1 and 2) wherein said solution comprises an ionic surfactant, a nonionic surfactant and a protein denaturant. The third step comprises measuring the resulting sample via immunoassay.
3. The treatment solution is diluted with the “reaction buffer” in step (3).
4. Endogenous antibodies inactivated in step (1) are polyclonal whereas the probe is a monoclonal antibody.

The instant claims are drawn to methods of detecting HCV or HBV in a biological sample by treating said sample with a “treatment solution” wherein said “treatment solution” inactivates antibodies present in the sample (see step 2 of claimed methods). Said sample is then subjected to an immunoassay that utilizes an antibody probe wherein the treated sample is added to a reaction buffer.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to points 1 and 4, there would be no discernable difference in the susceptibility to the denaturing effects of the treatment solution between polyclonal and monoclonal antibodies. The two types of antibodies have the same structure and differ only in the degree of homogeneity of their respective populations.

With regard to Applicant's argument that the probe will not be denatured since it is added to a treatment solution that has been diluted by a "reaction buffer", the recited claims (and the specification) provide no guidance as to the volume of "reaction buffer" used or the threshold concentrations of the treatment solution components below which they will no longer denature proteins. Therefore, since the specification gives no guidance as to what combination of components (and at what concentration), if any, would result in a treatment solution that would inactivate the endogenous antibodies present in the biological sample (step 2 of the claimed methods) but not inactivate the antibody probe subsequently used in the immunoassay (step 3 of the claimed methods) the specification is not enabling for the claimed method.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11, 34, 37-38 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 11, 37 and 41 as being rendered vague and indefinite by method steps (1) and (2). Steps (1) and (2) are still not linked by claim language. Therefore, it is still unclear whether the “treated virus-containing sample” of step (2) is the end product of step (1).

Claims 11, 37 and 41 are rendered vague and indefinite by the use of the phrase “reaction buffer”. Said term is not explicitly defined in the specification. Consequently, it is impossible to determine the components of said buffer and hence one cannot determine the metes and bounds of the claimed invention.

*Conclusion*

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No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman  
September 9, 2004

  
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